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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,642

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EXAMINER

KOSACK, JOSEPH R

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,642	Applicant(s) GALIS ET AL.	
	Examiner Joseph R. Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/29/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 14-33 are pending in the instant application.

Amendments

The amendment filed on January 29, 2009 has been acknowledged and has been entered into the application file.

Information Disclosure Statement

The Information Disclosure Statement filed on January 29, 2009 has been considered by the Examiner.

Previous Claim Rejections - 35 USC § 102

Claims 1-4 and 6-12 were previously rejected under 35 U.S.C. 102(b) as being anticipated by Schinstine et al. (USPN 5,776,747).

The claims have been cancelled in favor of new claims 14-33, therefore the rejection is rendered moot, and the rejection is withdrawn for claims 1-4 and 6-12.

For the new claims, the Applicant has traversed the rejection on the grounds that Schinstine et al. are not concerned with investigation and analysis, but are more concerned with providing a surface that is most conducive to the growth of a particular cell line to use as part of a bioartificial organ. Also, the Applicant traverses on the grounds that the substrate of Schinstine et al. does not have multiple microdomains in the form of a distinct pattern of discrete regions that vary in surface composition and/or physical properties.

The Applicant is incorrect that Schinstine et al. are not concerned with investigation and analysis. Schinstine et al. show the analysis of their bioartificial organ

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by conducting an immunofluorescence test in Example 1, columns 22-23. Additionally, the polymer substrate of Schinstine et al. has various pore sizes to allow compounds of different molecular weights into the bioartificial organ. See column 20, lines 18-44. Therefore, the bioartificial organ of Schinstine et al. would have different microdomains, which can be in a distinct pattern depending on the extrusion of the polymer. Therefore, Schinstine et al. will anticipate some of the new claims.

Previous Claim Rejections - 35 USC § 103

Claims 1-13 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Schinstine et al. (USPN 5,776,747).

The claims have been cancelled in favor of new claims 14-33, therefore the rejection is rendered moot, and the rejection is withdrawn for claims 1-13.

For the new claims, the Applicant has traversed the rejection on the same grounds as the anticipation rejection. The Examiner disagrees for the same reasons as stated above for the anticipation rejection. The rejection will be applied to new claims 14-33.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-18, 20-27, and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Schinstine et al. (USPN 5,776,747).

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The claims are drawn to a method for identifying substrates which will affect stem cell adhesion, survival, proliferation, or differentiation comprising contacting stem or undifferentiated cells with a combinatorial library comprising discrete regions varying in surface composition, microstructure, and molecules bound thereto. Dependent claims define the discrete regions, substrate, and differentiation. Also claimed are the combinatorial substrate libraries used in the method described above.

Schinstine et al. teach a method for making a bioartificial organ by attaching undifferentiated cells to a polymer, encapsulating the cells in the bioartificial organ, and causing growth and differentiation of the cells by adding ECM molecules to the bioartificial organ. Schinstine et al. also teach that endothelial cells can be realized by adding TGFB-1 to the undifferentiated cells. See Table 1 in column 16, and column 19, line 66 through column 21, line 44. Finally, Schinstine et al. teach the analysis of the differentiated cells by using immunofluorescence. See Example 1, columns 22-23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinstine et al. (USPN 5,776,747).

The claims are drawn to a method for identifying substrates which will affect stem cell adhesion, survival, proliferation, or differentiation comprising contacting stem or undifferentiated cells with a combinatorial library comprising discrete regions varying in surface composition, microstructure, and molecules bound thereto. Dependent claims define the discrete regions, substrate, which is a biodegradable polymer, and differentiation. Also claimed are the combinatorial substrate libraries used in the method described above.

Schinstine et al. teach a method for making a bioartificial organ by attaching undifferentiated cells to a polymer, encapsulating the cells in the bioartificial organ, and causing growth and differentiation of the cells by adding ECM molecules to the

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bioartificial organ. Schinstine et al. also teach that endothelial cells can be realized by adding TGFB-1 to the undifferentiated cells. See Table 1 in column 16, and column 19, line 66 through column 21, line 44. Finally, Schinstine et al. teach the analysis of the differentiated cells by using immunofluorescence. See Example 1, columns 22-23.

Schinstine et al. do not teach that the polymer substrate can be biodegradable.

To those of ordinary skill in the art, it would be obvious to use either a polymer that is biodegradable or a polymer that is not biodegradable. One advantage of a biodegradable polymer that is readily apparent to one of ordinary skill in the art is the ability to harvest either differentiated cells or as the skill in the art increases, whole organs, for transplantation into a subject in need with a reasonable expectation of success for harvesting the cells or organ.

Conclusion

Claims 14-33 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Joseph R Kosack/
Examiner, Art Unit 1626

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626